

CTSUS PROCESS CHECKLIST

CTSUS WEBSITES:

Public: <http://www.ctsu.org>

Members: <http://members.ctsu.org>
(Password Protected)

E-Mail: CTSUSContact@westat.com

CTSUS CONTACT INFORMATION

CTSUS CENTRAL REGULATORY OFFICE ADDRESS:

Coalition of National Cancer Cooperative Groups
1818 Market Street, Suite 1100
Philadelphia, PA 19103

CTSUS ADDRESS:

Westat
CTSUS Data Operations Center
1441 W. Montgomery Ave.
Rockville, MD 20850-2062

CTSUS Help Desk: 1-888-823-5923 (9:00am-7:00 pm, M-F, ET)
CTSUS FAX: 1-888-691-8039
CTSUS CENTRAL REGULATORY OFFICE FAX: 215-569-0206

CTSUS Patient Registrar: 1-888-462-3009 (9:00am-7:00pm, M-F, ET)
CTSUS Cell Phone: 301-704-2376 (For patient enrollments that must be completed within approximately 1 hour)
Please use 1-888-462-3009 for ALL other CTSUS enrollments

Account Management System (AMS)

- ☐ Link to the CTEP-AMS through www.ctsu.org
- ☐ Fill out online registration form
- ☐ Await CTEP-AMS/CTSUS confirmation emails
- *change temporary password to permanent password
(new members allow 2 business days to receive password)

SELECT AND DOWNLOAD PROTOCOL AND ASSOCIATED MATERIALS

- ☐ Protocol in full text
- ☐ Amendments
- ☐ Pharmacy Forms
- ☐ Case Report Forms
- ☐ Site Registration Documents
- ☐ Patient Enrollment Forms
- ☐ Adverse Event Forms
- ☐ Education and Training Materials
- ☐ Safety Updates (Drug Safety Notifications database is searchable by drug &/or protocol)

CONSULT PROTOCOL-SPECIFIC NOTES TO DETERMINE IF ANY MATERIALS FOR PROTOCOL MUST BE ORDERED FROM THE CTSUS (e.g. Quality of Life hard copy booklets) AND ORDER, IF NECESSARY.

DOCUMENTS, SUCH AS THE PROTOCOL CONSENT FORMS, MUST BE SUBMITTED FOR LOCAL IRB APPROVAL.

PROTOCOL-SPECIFIC SITE REGISTRATION

Select and print the following documents from the site registration category of the protocol-specific web page:

- ☐ CTSUS IRB Certification Form
- ☐ IRB Submission Application Template
(This is a tool to format your document for IRB review.)
- ☐ IRB/Regulatory Approval Transmittal Form
- ☐ Other protocol-specific documents needed for IRB approval

Consult the registration/randomization section of the CTSUS instructions for a complete list of required regulatory documents.

CTSUS Investigator Verification demonstrated by:

- ☐ PI has current FDA 1572 Form, CV, Financial Disclosure Form, and Supplemental Investigator Data Form on file at PMB
- ☐ Physicians other than PI who enroll patients have current documentation (see above) on file with the PMB
- ☐ All enrolling physicians are listed as active in the PMB database
- ☐ All enrolling physicians are members of a Cooperative Group/CTSUS
- ☐ All enrolling physicians are CTSUS members

Treating physicians are strongly encouraged to submit investigator registration documentation to the NCI/PMB Physician database, complete CTEP-AMS registration form, and be active in a Cooperative Group.

Call CTSUS to ensure that all physician information has been verified.

Fax or mail the following documents to CTSUS Central Regulatory Office:

- ☐ CTSUS IRB Certification Form or IRB Approval Letter
- ☐ IRB/Regulatory Approval Transmittal Form
- ☐ Copy of IRB approved informed consent: consents should follow the consent outlined in the protocol (if applicable)
- ☐ Any protocol-specific requirements

The CTSUS Members Website will provide a complete list of documents required for each protocol.

PATIENT ENROLLMENT/REGISTRATION

Download the following documents to assist with screening patients for eligibility:

- ☐ Time and Event Schedule
- ☐ Protocol Card, which summarizes eligibility criteria, required laboratory tests or procedures, treatment plan, and schema

NOTE: Always consult latest version of the protocol as the ultimate authority.

Ensure the following:

- ☐ Informed consent is obtained
- ☐ Pretreatment evaluations are complete
- ☐ Eligibility criteria are satisfied
- ☐ CTSUS has received and approved required documents to date
- ☐ Site registration approval notification has been received from the CTSUS Central Regulatory Office

Inform the CTSUS Data Operations Center that a patient enrollment is forthcoming and submit the following:

- ☐ CTSUS Patient Enrollment Transmittal Form
- ☐ Protocol-Specific Eligibility Checklist
- ☐ Other forms or documents as required by the protocol

Enrolling site receives from the CTSUS via phone, fax, and/or e-mail:

- ☐ Patient Identification Number
- ☐ Randomization, as appropriate

Continuing Data Submission

- ☐ CRFs
- ☐ AdEERS
- ☐ After enrollment, all CRFs must be mailed to the CTSUS Data Operations Center

Audit→Validate

Financial